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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/544,150

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EXAMINER

MAHYERA, TRISTAN J

ART UNIT

PAPER NUMBER

1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/544,150	Applicant(s) SMITH, FRANCIS X.	
	Examiner TRISTAN J. MAHYERA	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 1 and 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/29/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-11 are pending. Claims 1-11 are examined on the merits.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(a-d) is acknowledged.

Specification

The disclosure is objected to because of the following informalities: The use of the trademarks POLYQUAD and CREMOPHOR have been noted in this application. A trademark should be capitalized wherever one appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Appropriate correction is required.

Claim Objections

Claims 1 and 9 are objected to because of the following informalities: The “or” in line 2 of Claim 1 is believed to be “of”. The “enhanced” in line 2 of Claim 9 is believed to be “enhancer”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte*

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Hasche, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 9 recites the broad recitation “0.0001 to about 10”, and the claim also recites “0.001 to 10” which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over MOWREY-MCKEE et al. (US 5,817,277 see PTO-892) in view of YANOVSKAYA et al. (Effect of Low-Dose Emoxypine and Pyridoxine Hydrochloride on Human Cataract and Glaucoma, 1993 see PTO-892).

MOWREY-MCKEE teaches a method and solution for disinfecting contact lens comprising 0.00001 to 0.1 percent of PHMB (polyhexamethylene biguanide), which reads on the at least 0.0001% and between 1 and 10,000 ppm of a preservative. See

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e.g. claims 1 and 3: instant claims 1 and 2. The solution is used on contact lens, which are in a container (i.e. vial) with a sufficient amount of the solution to cover the lens, which reads on the method of contacting a contact lens. See e.g. col. 3 line 66 to col. 4 line 4: instant claim 11. A buffer (e.g. sequestering agent) is added to the solution. See e.g. claims 1, 6 and 7. The sequestering agent is taught to be citric acid. See e.g. col. 2 lines 50-53: instant claim 8. The buffer is further tromethamine, which is also known as TRIS buffer and is used at 0.5%, which reads on the physiological buffer in instant claim 4. See e.g. claim 1: instant claims 3 and 4. Additional ingredients which would not affect the basic and novel characteristics of the active ingredients described earlier, such as tonicity agents, surfactants and viscosity inducing agents, which may aid in either the lens cleaning or in providing lubrication to the eye are taught. Suitable tonicity agents include sodium chloride, potassium chloride, glycerol or mixtures thereof. The surfactants are taught to be polyoxyethylenes. See e.g. Col. 3 lines 20-25 and 33-43: instant claims 7 and 10.

MOWREY-MCKEE does not explicitly teach the use of Vitamin B (e.g. pyridoxine, vitamin B6).

YANOVSKAYA teaches the use of pyridoxine, vitamin B6 for the treatment of cataracts, glaucoma, keratitis and inflammatory eye diseases. See e.g. Abstract: instant claims 1, 9, 10 and 11. The pyridoxine is in concentrations of 0.2 to 0.02%, which reads on the 0.001 to 10% in claims 1 and 9. The pyridoxine is administered as drops into a patients eyes. See Abstract and Methods.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a ophthalmic solution comprising Vitamin B6 (pyridoxine), as taught by MOWREY-MCKEE in view of YANOVSKAYA. One of ordinary skill in the art at the time the invention was made would have been motivated to use Vitamin B6 in a contact lens solution, because it is in a eye drop solution and treats cataracts, glaucoma, keratitis and inflammatory eye diseases as taught by YANOVSKAYA. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over MOWREY-MCKEE in view of YANOVSKAYA as applied to claims 1-4 and 7-11 above, and further in view of De BRUIJI et al. (US 6,162,393 see PTO/SB/08).

De BRUIJI teaches the use of glycerin and decanedioic acid for use in contact lens solutions. The contact lens solution comprises between 0.01 to 5.0% glycerin and 0.01 to 2.0% decanedioic acid. See e.g. claims 5 and 6: instant claims 5 and 6. The glycerin can reduce any minor toxic effects that a disinfectant agent might have on mammalian cells. See e.g. Example 4. Decanedioic Acid improves the ocular comfort of contact lens solutions. See e.g. Example 5.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a ophthalmic solution comprising vitamin B and the addition of glycerin and decanedioic acid, as taught by MOWREY-MCKEE in view of

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YANOVSKAYA and in view of De BRUIJL. One of ordinary skill in the art at the time the invention was made would have been motivated to use glycerin and decanedioic acid because glycerin can reduce any minor toxic effects that a disinfectant agent might have on mammalian cell and decanedioic Acid improves the ocular comfort of contact lens solutions, as taught by De BRUIJL. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 10 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 11 of copending Application No. 11/620318. This is a

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provisional double patenting rejection since the conflicting claims have not in fact been patented.

The claims both state” “A contact lens treatment solution comprising a Vitamin B Complex and a tonicity agent.”

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 11/620318. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications teach the use of a preservative and preservative enhancer, glycerin and decanedioic acid, surfactants, buffers, and a tonicity agent (e.g. chloride). The applications differ because the range of the preservative and preservative enhancer in the copending application is broader (0.00001 vs. 0.0001), yet fully encompassing of the instant range.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRISTAN J. MAHYERA whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Friday 9am-7pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P. WOODWARD can be reached on 571-272-8373. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tristan J Mahyera/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615